UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	Judge Patti B. Saris
	Chief Magistrate Judge Marianne B. Bowler
	[FILED UNDER SEAL PURSUANT TO COURT ORDER]

DECLARATION OF RAYMOND S. HARTMAN
IN OPPOSITION TO
DEFENDANTS' MOTIONS
FOR SUMMARY JUDGMENT

Executive Summary

I have been asked by Counsel to the Plaintiffs and the Plaintiff Class to review the expert declarations and legal motions put forward by the Track 1 Defendants in support of summary judgment and analyze and respond to specific issues involving matters of economic theory and fact. In so doing, I find that the economic assertions and arguments presented in each of the motions and declarations are either irrelevant, misleading or laden with faulty analysis. Relying on previous testimony, as well as additional analysis presented herein, I conclude that the Defendants' economic arguments fail and are without merit.

My conclusions are the following:

(a) Defendants claim that Plaintiffs endorse a theory that states "AWP should equal ASP" which they then assert is inconsistent with my 30% liability yardstick. These claims are false; neither I nor the Plaintiffs have ever suggested this. As such, these claims misstate the record before this Court and misinterpret my formulaic methodology.

(b) Defendants argue that HCFA and Medicare knew of and were not deceived by the alleged spreads of Part B drugs. This argument is flawed and relies on an incomplete and misleading analysis of the content and context of publicly available documents.

(c) Defendants assert that private sector third-party payers with staff model HMOs that purchased Part B drugs knew of and were not deceived by the alleged spreads. This conclusion is incorrect. Regardless of the fact that staff model HMOs may have purchased some drugs at issue at a discounted price, the Defendants do not present any evidence that this has resulted in any reduction in reimbursement rates. I show that it has not.

(d) Defendants state that since Medicare reimbursement of multi-source drugs is based on the median generic AWP, this defeats any benefits alleged to flow from the AWP inflation scheme. This assertion is based on an incomplete understanding of the market; an incomplete understanding of my methodology; and flawed data analysis; and is therefore incorrect.

(e) Defendants assert that the alleged behavior is economically rational. Though the behavior at issue may be found economically rational, that finding does not trump the law. This argument fails based on the fact that numerous business activities, considered economically rational, in this market and other markets have been found to be in violation of the law.

(f) Defendants make a claim that spreads expressed relative to ASP rather than relative to AWP are "greatly exaggerated." This erroneous claim is easily defeated by a simple mathematical relationship that shows it does

not matter whether spreads are calculated with respect to ASP or AWP; liability and damages are identical either way.

(g) Defendants assert that BMS did not report AWPs to the price reporting services; it reported WAC. Therefore, BMS contends that it had no control over how AWPs were set and could not have participated in the AWP scheme. Given the fact that list prices serve as important signals in this market, and the fact that there is a well understood formulaic relationship between AWP and WAC, this argument is implausible and not credible as a matter of economics and business practices.

Nothing I have reviewed to date in the Defendants' motions or reports, including the issues noted above as well as additional data-related issues, would cause me to change my opinions regarding my formulaic methodologies or the process of calculating damages based on those methodologies.

I. Introduction and Overview of this Declaration

1. My name is Raymond S. Hartman. I have previously presented my qualifications to this Court and have submitted Affirmative and Rebuttal Declarations in Support of Class Certification and an Affirmative Declaration demonstrating liability and calculating damages for the Sub-Classes as certified by Judge Saris in her August 16, 2005 *Memorandum and Order*.

2. I have been asked by Counsel to the named Plaintiffs and the Plaintiff Class to review the expert declarations and legal motions put forward by the Track 1 Defendants in support of summary judgment. I have been asked to conduct those analyses and discuss those issues that I deem appropriate in order to respond to the Defendants' Joint Motion for Summary Judgment;[1] to specific individual Track 1 Defendants' Motions for Summary Judgment if appropriate;[2] and to the declarations submitted by experts on behalf of the Defendants.[3] I analyze and respond to specific issues raised in Defendants'

[1] Memorandum of Law in Support of Track 1 Defendants' Joint Motion for Summary Judgment, March 15, 2006 (*Joint Motion*). *In re: Pharmaceutical Industry Average Wholesale Price Litigation,* United States District Court, District of Massachusetts, MDL No. 1456, Civil Action No. 01-12257

[2] AstraZeneca Pharmaceuticals LP's Memorandum of Law in Support of its Motion for Summary Judgment; Memorandum in Support of GSK's Motion for Summary Judgment as to all Claims asserted by Plaintiffs David and Susan Ruth Aaronson and Certain Claims Asserted by Classes 1 and 2 (*GSK Motion for Summary Judgment*); The BMS Defendants' Memorandum of Law in Support of their Motion for Summary Judgment (*BMS Motion for Summary Judgment*); The Johnson & Johnson Defendants' Memorandum in Support of their Motion for Summary Judgment as to Class 1 and Class 2; Memorandum in Support of Schering-Plough Corporation's and Warrick Pharmaceuticals Corporation's Motion for Summary Judgment as to Class 2 Claims; all *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, United States District Court, District of Massachusetts, MDL No. 1456, Civil Action No. 01-12257, March 15, 2006.

[3] On behalf of the Defendants jointly: the Declaration of Eric M. Gaier, Ph.D., In Support of Track 1 Defendants' Joint Motion for Summary Judgment (*Gaier Declaration*). On behalf of specific individual Defendants: the Declaration of Jayson S. Dukes in Support of the Johnson & Johnson Defendants' Motion

motions, if those specific issues involve matters of economic theory and fact that have not been developed in the related supporting expert declarations.

3. This Declaration proceeds as follows. In Section II, I identify the issues raised and arguments made by Defendants' motions and Defendants' experts. I discuss the reasons why these issues are irrelevant and why the Defendants' arguments fail. In Section III, I present additional detail for selected issues discussed in Section II. I also address selected data concerns raised by Defendants' experts in Section III. My conclusions are summarized in the Executive Summary above. Attachment A identifies materials cited in this Declaration.

II. Incorrect Assertions Made by Defendants and the Incorrect Analytic Results Put Forward by Defendants' Experts to Support those Assertions

4. In this Section, I introduce the assertions made and issues raised by Defendants through the three venues they have used: their Joint Motion for Summary Judgment; the specific individual motions for summary judgment filed by each of the Track 1 Defendants and the declarations put forward by their experts. I focus upon those assertions with economic content.[4]

A. Defendants Incorrectly Argue that Plaintiffs Argue that AWP should Equal ASP

5. Track 1 Defendants erroneously assert that Plaintiffs believe that "AWP should equal ASP."[5] This is a serious mischaracterization of my testimony at this stage of the litigation. In all analyses put forward in my Affirmative and Rebuttal Declarations in

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for Summary Judgment As to Class 1 and Class 2 (*Dukes Declaration*); Merits Report and Declaration of Gregory K. Bell, Ph.D., for the Bristol-Myers Squibb Group (*Bell Declaration*); the Declaration of Sumanth Addanki, Ph.D., for the Schering-Plough Group (*Addanki Declaration*); all *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, United States District Court, District of Massachusetts, MDL No. 1456, Civil Action No. 01-12257, March 15, 2006.

[4] My expertise as an economist does not allow me to address assertions regarding questions of law, such as the prevailing statute of limitations, whether the named Plaintiffs are adequate representatives of the relevant Classes and whether the federal government was deceived, as a matter of law.

[5] See Section I heading, *Joint Motion*, page 9. In making this assertion, Defendants apparently draw upon the confused and frequently incorrect Declaration of Dr. Addanki. Dr. Addanki certainly does not comprehend the allegations in this matter. For example, he states at ¶ 17 of his Declaration, "The Complaint alleges a scheme in which the measure of the average *wholesale* price has been manipulated, i.e., that the AWP does not, in fact, represent what *wholesalers* obtain from providers and other intermediaries. The price received by the *manufacturers* has no bearing on this alleged manipulation."

It is unclear what Dr. Addanki is talking about. That is not the alleged AWP inflation scheme. The allegations are laid out clearly in my September 3, 2004 Declaration in Support of Class Certification, as cited below in footnote 6. Also, see Section IV of the Third Amended Master Consolidated Class Action Complaint, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, United States District Court, District of Massachusetts, MDL No. 1456, Civil Action No. 01-12257, October 17, 2005, beginning at page 42.

Support of Class Certification and in my December 15, 2005 Declaration on Liability and Calculation of Damages, **I have never taken the position** that Defendants should have **set the "AWP equal to the ASP."** At all places in my Declarations, I have made explicit the following industry practice and knowledge: AWP has been a "sticker price" or "list price" for all drugs (by NDC); other list prices, most importantly WAC, are related formulaically to and are less than the AWP (AWP > WAC); transactions prices (including AMP and ASP) are negotiated off AWP and are less than AWP and WAC.[6] I have articulated this same position in my most recent deposition.[7]

6. My formulaic methodology is straightforward.

- The AWP has been taken by the industry, including the public and private sectors, to be *a signal* for transactions prices (EAC and ASP), particularly the acquisition costs of providers of Part B drugs.[8]
- It is understood that the signal is not perfect, but it has been taken to be sufficiently accurate for reimbursement, despite its imperfection. Defendants' Expert Mr. Young has made this clear.[9]
- While imperfect, prior to the AWP inflation scheme, the signal provided the expectation that the AWP of single-source physician-administered drugs exceeded the provider acquisition cost (EAC or ASP) by 15-25%.
- Using the threshold of 30%, the formulaic methodology put forward in my December 15, 2005 Declaration finds AWP inflation subject to liability when the revealed spread ((AWP-ASP)/ASP) exceeds 30%.
- Once actual spreads are found to exceed 30%, the related AWP is found to have been inflated to an extent not fully understood by public and private sector payers. Hence, those public and private payers could not and did not adequately respond to adjust their reimbursement practices to the AWP inflation scheme.
- If I find liability (a spread in excess of 30%), I calculate damages. The Medicare damages are set forth by statute explicitly and without ambiguity.

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[6] See, for example, the September 3, 2004 Declaration of Raymond S. Hartman in Support of Class Certification, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, United States District Court, District of Massachusetts, MDL No. 1456, Civil Action No. 01-12257, ¶ 30. It has been understood that providers acquire such drugs at somewhat less than WAC. See also, my September 3, 2004 Declaration, Attachment D, ¶ 2, and my December 16, 2004 Rebuttal Declaration, ¶ 15, Section D.

[7] Deposition of Raymond S. Hartman, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, February 27, 2006, pp. 670 – 686.

[8] See pp. 9-10 of my September 3, 2004 Declaration in Support of Plaintiffs' Motion for Class Certification. See also Chapter 9, "Medicare payments for outpatient drugs under Part B" of Medicare Payment Advisory Commission (MedPAC), *Report to the Congress: Variation and Innovation in Medicare*, June 2003, which notes: "Most private payers are still using AWP-based payment methods similar to the Medicare model" (p. 164).

[9] See ¶ 33 and Attachment K of my December 15, 2005 Declaration on Liability and the Calculation of Damages in this matter.

Reimbursement is to be at "the lower of the EAC[10] or the AWP" (or 95% of AWP over 1998-2003 or 85% of AWP over 2004; see footnote 13 of my December 15, 2005 Declaration).

- Under Medicare Part B reimbursement, Plaintiffs do not assert that the AWP should = ASP. It is clear by the liability threshold and by an understanding of the markets in question, that such an equality does not (nor are Plaintiffs suggesting that it should) occur. However, under Medicare Part B, reimbursement should be set at the lower of the AWP (or a percentage thereof) and the EAC = ASP, so that if liability is demonstrated and reimbursement is paid at x%*AWP, calculation of damages is determined directly by Statute.

7. Furthermore,, Defendants erroneously argue that "a finding that AWP was intended to mean ASP would impose liability on virtually every Medicare Part B eligible drug."[11]

Since I never assumed that AWP "means" or "equals" ASP, my December 15, 2005 Declaration on Liability and Calculation of Damages finds and imposes no liability for any Medicare Part B drug whose spread of AWP relative to its ASP is not inflated, that is, did not exceed the liability threshold of 30%.[12]

If, however, the spread is excessive (> 30%), I do find liability. At that point I assess damages according to the Medicare Statutes; that is, I measure damages as the amount by which the AWP (or the relevant percentage thereof) exceeds EAC = ASP. The assumption underlying this method is that had HCFA and Medicare understood sufficiently[13] the general extent to which the actual spreads on physician administered drugs were *mega-spreads*, they would have more aggressively undertaken the surveys to calculate EACs and impose the lesser of AWP (or a percent thereof) and the EAC practice for reimbursement.

8. Defendants continue their distorted characterization of Plaintiffs' position, stating, "Plaintiffs' proposed construction of the regulation [i.e., AWP = ASP] is entirely inconsistent with HCFA's interpretation of the regulation. Between 1992 and 1997, HCFA did not implement reimbursement on the basis of EAC, but rather reimbursed providers for physician-administered drugs at 100% of AWP."[14]

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[10] Attempts to assert that the "actual charge" differ from the EAC (for 1998-2003) fail for reasons discussed in my December 15, 2005 Declaration on Liability and the Calculation of Damages, footnote 14.

[11] *Joint Motion*, pp. 1-2.

[12] See my December 15, 2005 Declaration on Liability and Calculation of Damages, ¶¶ 56-60. In my February 3, 2006 Supplemental Declaration on Liability and Calculation of Damages, I was asked to calculate damages under Medicare Part B reimbursement, if as a matter of law, it was determined that reimbursement rates for all Part B drugs should have been the lower of the AWP (or 95%AWP or 85% AWP) and the EAC (= ASP), regardless of whether the AWP exceeded the yardstick spread of 30%.

[13] I discuss how much HCFA and Medicare knew in Section II.C below.

[14] *Joint Motion*, p. 10.

Plaintiffs' construction of the relevant Medicare statute as implemented in my damage analysis for that period of time (indeed for all periods during the Damage Period in which the Statute was revised) is based upon Statute, as cited in footnote 13 of my December 15, 2005 Liability Declaration. This construction is not "inconsistent with HCFA's interpretation;" **it implements it explicitly**. The Statute reads:

> "Payment for a drug … *is based on the lower of the estimated acquisition cost (EAC) or the national average wholesale price [i.e., AWP][15] of the drug.* … For multiple-source drugs, payment is based on the lower of the estimated acquisition cost … or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug." (Source: 42 CFR 405.517, Revised October 1, 1996; emphasis added)

Contrary to Defendants' assertion,[16] Plaintiffs do understand the fact that "HCFA has always interpreted AWP to mean something different than ASP." Indeed, my formulaic methodology explicitly incorporates into the calculation of damages the fact that AWPs exceed ASPs, hence EACs. Liability is alleged not because AWP exceeds the ASP; rather liability is alleged because it exceeded ASP by the unreasonably and unexpectedly substantial amounts reflected in the "mega-spreads" recognized by Judge Saris and Dr. Berndt. Once liability is determined, damages occur precisely because reimbursement occurred at the higher of the artificially inflated AWP rather than "the lower of the EAC and or the national average wholesale price [AWP] of the drug." The Judge has agreed with this interpretation of the economic implications of the Statute.[17]

9. Indeed, individual Defendants recognize that my formulaic methodology admits to the fact that AWP exceeds ASP and that it implements damage calculations only when

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[15] Note that the average wholesale price (AWP) does appear in the 1991 statutory revision, as is recognized in Defendants' *Joint Motion* (pp. 4, 9). The fact that the *Joint Motion* states that "AWP appeared in the Medicare statute for the first time in 1997" on page 12 is contradictory and must be a typographical error. Note further that Defendants feebly attempt (at p. 12 of their *Joint Motion*) to imply that "the statute did not include an express definition of the term [AWP]." This innuendo does not work. Regardless of the "express definition," the industry has had a very definite understanding of AWP throughout the Damage Period; indeed, Defendants quote (*Joint Motion* at p. 13): "A House Report … stated 'The AWPs are reported by drug manufacturers to organizations that publish the data in compendia.'"

Neither I nor the Plaintiffs disagree with this characterization.

[16] *Joint Motion*, pp. 11-12.

[17] At pp. 58-59 of the *Memorandum and Order*, Judge Saris states for Sub-Class 1: "The Court is satisfied that as to the Medicare Part B beneficiary class, a class action is a superior method to resolve the dispute. Defendants have not identified any plausible individual issues that will arise with regard to these class members other than their proofs of damages, which may entail reviewing documents to determine whether each patient was required to pay a percentage-based co-pay and whether each has supplemental insurance. **These damages calculations will be largely formulaic.** Even if some corroboration and individualized attention is necessary, it is unrealistic to expect millions of beneficiaries across the nation to repeatedly prove these claims. The number of drugs at issue in the Medicare Part B context is limited to about seventeen, so even if deciding spreads by individual NDCs is necessary, it would not be unmanageable" (emphasis added). For Sub-Class 2, she states: "**Again, the common factual issues (as outlined in the previous section) predominate**, in that the TPPs are required by contract to supplement Medicare drug co-payments" (emphases added).

AWP is excessively inflated above ASP. For example, in its Motion for Summary Judgment, GSK makes the legal assertion that it is entitled to summary judgment on those drugs whose spread was less than my liability threshold of 30%.[18]

B. Defendants Incorrectly Assert that My 30% Liability Yardstick Is Inconsistent with My Calculation of Damages under Medicare Reimbursement

10. Defendants incorrectly assert[19] that my use of a threshold spread of 30% for a determination of liability is inconsistent with my calculations of damages as (x%*AWP – ASP)[20] under the Medicare Statutes. They incorrectly conclude that "Plaintiffs find no regulatory or statutory support for their AWP-equals-ASP theory, [and] they also have no support from their own expert."

As discussed above, Plaintiffs do not have an "AWP-equals-ASP theory." Nor does Plaintiffs' reliance upon the Medicare reimbursement Statutes **for the calculation of damages** contradict the use of the threshold spread of 30% for **a determination of liability**. The apparent confusion seems to derive from the incorrect interpretations of Dr. Addanki. My methodology is not so difficult that Defendants can so completely misinterpret it. I must conclude the misinterpretation is deliberate.

I reiterate how these market realities are incorporated into my formulaic methodology in ¶ 6 above.

C. Defendants Incorrectly Assert that HCFA and Medicare Knew of and Were Not Deceived by the Alleged Spreads on Part B Drugs and Had the Duty to Mitigate the Impact of the Spreads

11. Defendants argue[21] that HCFA and Medicare knew that AWP exceeded EAC and ASP; that they were aware of survey evidence that AWP exceeded EAC and ASP, at times "substantially." As a result, Defendants assert, incorrectly, that HCFA and Medicare were not deceived by the AWP inflation scheme, and that HCFA and Medicare

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[18] *GSK Motion for Summary Judgment*, pp. 15-16. While it is true that those drugs (by NDC and year) for which spreads did not exceed 30% were not considered subject to the AWP inflation (again, by NDC and year) in my December 15, 2005 Declaration on Liability and Calculation of Damages, I was informed by Counsel that, as a matter of law, such drugs may still be subject to damage calculations. I was therefore asked by Counsel to perform the damage calculations found in my February 3, 2006 Supplemental Declaration on Liability and the Calculation of Damages. I continue to understand that this issue is a matter of law, and that I may be asked to make further refinements and calculations depending upon legal conclusions yet to be made. In addition, to date we still have not received data for all of GSK's drugs for all years (this is true for other manufacturers as well).

[19] *Joint Motion*, p. 14.

[20] Where x% = 100% (1991-1997), 95% (1998-2003) and 85% (default value for 2004, with a range of 80%-95%).

[21] *Joint Motion*, Section II.

had the information, ability and duty to mitigate the reimbursement impacts of the alleged AWP inflation scheme.[22]

In making these assertions Defendants rely principally upon their expert Dr Addanki, who expends considerable energy revisiting facts that have either been explicitly cited in my Declarations to date[23] and/or have certainly not been denied by my analysis. Dr. Addanki appeals (in his footnote 16) to "some 33 publications containing information on spreads." Note that only a subset of these studies present original survey information.[24]

I reiterate and analyze the 33 studies identified by Dr. Addanki in Attachment C. Indeed, I have added additional studies. While even other studies could be added to this list, I believe my current list to be sufficiently representative.[25] From this list I conclude the following:

a) Many (33%) of the OIG studies focus upon self-administered drugs, branded and generic rather than the drugs subject to this litigation. These studies found that the spreads on branded self-administered drugs through the end of the 1990s and after 2000 were within my yardstick for a finding of causation and liability. Furthermore, these studies found that until the mid-1990s, the spreads of generic self-administered drugs were within my liability yardstick.

   It was only in those surveys between 1996 and 2000 that the increased spreads on generic self-administered drugs became evident.

b) Approximately 44% of these studies focus upon a broader cross-section of physician-administered drugs. I relied upon two of them, cited by Dr. Addanki. In an attempt to look at trends over the decade, I identified one study implemented early in the Damage Period (the 1992 OIG report on chemotherapy drugs) and one study implemented late in the damage period (the 2001 ASCO survey on chemotherapy drugs). Both surveys found spreads within my liability yardstick for single-source physician-administered drugs.[26]

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[22] As in the *Joint Motion*, GSK in its Motion incorrectly argues that the government's knowledge defeats the assertion that the reported AWPs were deceptive or unfair (*GSK Motion for Summary Judgment*, pp. 10-12).

[23] See my December 15, 2005 Declaration of Liability and Calculation of Damages, ¶¶ 59.b) – 59.c); my September 3, 2004 Declaration in Support of Class Certification, ¶¶ 29-30 and ¶¶ 21-22 of Attachment D to that Declaration.

[24] The other studies make use of data developed in this subset.

[25] I place greater weight on the information content of surveys, rather than newspaper and magazine articles.

[26] Note that the *BMS Motion for Summary Judgment* (at p. 18) misstates the findings of the 1992 study, **incorrectly attributing spreads of more than 400% for Cytoxan and Rubex,** both multi-source physician-administered drugs (hence, not included in my yardsticks, as discussed in ¶ 60 of my December 15, 2005 Declaration on Liability and Calculation of Damages).

For examples, according to Appendix III of the 1992 OIG report, invoice costs of generic Cytoxan were 20%-59% below AWP; invoice costs for generic Rubex were 56%-59% below AWP. The spread (relative to ASP) implied by these survey results are the following: for generic Cytoxan (25% to 144%) and for

c) Since Dr. Addanki has introduced a variety of reports/articles summarizing spreads at dates **within these two end points**, surveys which I did not include, it is useful to examine some of those survey results. I find that these additional studies support my findings in the two reports that I did cite in my earlier Declarations (for the full citation, see Attachment C).

- The Bill Alpert article in Barrons finds spreads for single-source physician-administered drugs to be 10%-20% below AWP (which is within my liability threshold of damages as calculated off AWP – see Section II.G below). The spreads for generic physician-administered drugs ranged from 60-85% below AWP.
- The OIG Report for December 1997 finds spreads average 22.5% off AWP for 11 single-source physician-administered drugs in 1995. The spreads for 9 multi-source physician-administered drugs ranged from 60-95%. For these same drugs in 1996, OIG finds spreads that averaged 19.5% off AWP for single-source drugs and averaged 64% for multi-source drugs.[27]

d) Based upon these studies, I conclude that the publicly available survey evidence generally informing "the government, policy makers, and industry participants"[28] about spreads on single-source physician-administered drugs over much of the damage period suggested that the spreads were not excessive.

e) Dr. Addanki also put forward (in his Exhibit 2) a variety of survey results that focus upon the drug albuterol and its spreads, finding them to be quite large beginning in 1996 and growing considerably over time. I reiterate those citations with my additions in Attachment C; these albuterol reports account for approximately 22% of those cited by Dr. Addanki.

f) While Dr. Addanki has correctly cited the existence of the large spreads for albuterol specifically, proper context must be given. These spreads began to reach public awareness in 1996. However, these spreads were for **a single generic physician-administered drug**, which is obviously of interest to Dr. Addanki's client, Schering-Plough. The observation that **the spreads for a single drug were large would certainly not provide sufficient evidence** to "the government, policy makers, and industry participants" **that all spreads on all physician-administered drugs were large**. Indeed, the survey result of ASCO, which looked at a broader cross section of drugs at a later point in time, found just the opposite.

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generic Rubex (127% to 144%). The spreads found on page 6 of the report for these drugs are 28% for generic Cytoxan (500 mg) and 144% for generic Rubex (70 mg).

[27] The range of spreads for single-source drugs was 15%-29% in 1995 for 10 drugs. The spread for one single-source drug in 1995, Novantrone, was 52%; however, this seems to be an anomaly, since this spread drops to 19% in 1996. The range for single-source drugs in 1996 was 13% to 30%; the range for multi-source drugs was 44%-92%.

[28] Quotation from ¶ 7 of Dr. Addanki's Declaration, where he incorrectly concludes that "There is ample evidence that the government, policy makers, and industry participants were well aware of the sometimes substantial differences between reimbursement rates for physician-administered drugs and the prices actually received by manufacturers."

g) Medicare would not alter their reimbursement practices based upon a single generic Part B drug or on several multi-source generic drugs beginning to be cited in 1996. Hence, the substantial evidence that the spread on albuterol was large in 1996 and became a mega-spread by 2000 (whether calculated relative to AWP or ASP) was not sufficient to make it cost effective for public and private-sector payors to alter their entire claims reimbursement practices for physician-administered drugs generally.[29] Likewise, the sporadic survey information that the spreads on some multi-source drugs were large for some providers over the 1990s was not sufficient to make it cost effective for payors to alter their entire claims reimbursement practices for physician administered drugs generally.

h) Medicare is a large governmental and political organization. While we are focusing on one aspect, reimbursement for physician-administered drugs, it is an aspect that is small compared to all of the daunting issues that Medicare deals with on a continual basis. The reimbursement for Part B drugs truly falls into the category of "the importance of being unimportant." As noted in a recent *Health Affairs* article: "Prior to the historic moment ushered in by MMA, the inefficiencies associated with using a rigged pricing system for injectable drugs have been tolerated as problem stepchildren within Medicare's large and dysfunctional family."[30] It is this toleration that Defendants have exploited by their AWP inflation scheme.

i) Defendants make the analytically unfounded and self-serving leap from survey information regarding spreads on self-administered generic drugs Medicaid drugs and selected generic physician-administered drugs to all physician-administered drugs reimbursed under Medicare Part B. While hindsight, illuminated through discovery in this litigation and other litigation,[31] demonstrates that the substantial spreads found with generic self-administered drugs and selected generic physician-administered drugs in the latter half of the 1990s were indeed reflected in spreads for physician-administered drugs generally, such a general understanding simply did not exist at that time. No consistent survey information supported such an understanding. Anecdotal information for individual Part B drugs was not sufficient to change the overall expectation throughout the 1990s that the AWP provided *a reasonable expectation* for the EAC of Part B drugs. Indeed, it is impossible to explain why Medicare, if as well informed as posited by Dr. Addanki, would have allowed itself to be economically injured to the extent it was in the Lupron and Zoladex matters[32] and in the case of Vincasar.[33]

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[29] See p. 6 of Attachment K to my December 15, 2005 Declaration on Liability and the Calculation of Damages. See also footnote 39 below.

[30] J.D. Kleinke, "Re-Naming and Re-Gaming: Medicare's Doomed Attempt to Reform Reimbursement for Injectable Drugs," *Health Affairs*, December 8, 2004.

[31] See the subsequent footnote.

[32] See ¶ 53.b) of my December 15, 2005 Declaration on Liability and Calculation of Damages and *United States of America v. TAP Pharmaceutical Products, Inc., Sentencing Memorandum of the United States*, United State District Court for the District of Massachusetts, Eastern Division, Criminal Action, No. 01-CR-10354-WGY (hereafter *Lupron Sentencing Memorandum*).

j) As noted by Defendants, there were certainly attempts to inform HCFA and Medicare of the AWP inflation scheme. Indeed, as made clear in a "letter from Ven-A-Care to Dr. Bruce Vladeck of HCFA dated October 2, 1996" cited by BMS at page 18 of their Memorandum:[34]

- "AWP has become the benchmark in the industry for establishing pharmaceutical reimbursement. ... Unfortunately, the pharmaceutical manufacturers have circumvented the intent of the government's reimbursement methodology by falsely reporting inflated AWP pricing information enabling providers to reap windfall profits from the provision of infusion and respiratory drugs." (at p. 3)

- "The manufacturers are and have been reporting false and fraudulent drug pricing information, including a drug's AWP, direct price, "DP", and wholesaler acquisition cost, "WAC" ... By falsely inflating drug pricing information, the drug manufacturers increase the profit margins enjoyed by their customers, thereby driving demand upward and increasing utilization." (at p. 4)

- "Seizing the opportunity to exploit their control over drug prices, the drug manufacturers have in some instances, reported higher prices for generic products than the equivalent brand." (at p. 4)

- "The drug manufacturers are further exploiting their ability to falsify pricing information by using their falsifications of AWP as a marketing tool. ... Our company has been solicited on numerous occasions by drug manufacturers who brag about their use of falsely inflated pricing information as a reason for purchasing their product over a competitor's with a lower AWP." (at p. 5)

- "We understand that the HCFA may be examining a plan that would, for Medicare only, abandon the AWP reimbursement methodology. ... this approach is based on the erroneous assumption that there is something wrong with the historical concept of AWP. The damage to the Medicare and Medicaid programs is being caused by false pricing information being submitted by the drug manufacturers rather than truthful representations of AWP. ... any plan must insure that there is truth and honesty in drug pricing information provided by the manufacturers and upon which reimbursement decisions are based." (at p. 5)

k) Defendants take such discovery materials as demonstration that HCFA and Medicare were not deceived by the alleged AWP inflation scheme. Defendants

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[33] See ¶ 53.a) on my December 15, 2005 Declaration on Liability and Calculation of Damages.

[34] Letter from Z. Bently, Ven-A-Care to Dr. Bruce Vladeck, HCFA, dated October 2, 1996 in re Excessive Reimbursements for Certain Pharmaceuticals by the Medicare and Medicaid Programs. Also marked as Exhibit 34 to my deposition in this matter, February 27, 2006 and Exhibit L to Steven Edwards Declaration filed with the *BMS Motion for Summary Judgment*, March 15, 2006.

are missing the point. The fact is that institutional knowledge is slow to be disseminated and even slower to be acted upon. It was the slowness of Medicare and HCFA to understand the existence of the AWP inflation scheme, to understand the economic injury induced by the scheme and to act upon that which has been exploited by Defendants through the AWP inflation scheme.

l) Indeed, as demonstrated in the next section, private sector, profit-maximizing payers were not more effective in assimilating, institutionally-sharing and acting upon the same information. Specifically, the reimbursement practices and procedures of Massachusetts' TPPs with staff-model HMOs did not incorporate similar information into their claims reimbursement policies, even though those payors clearly possessed better spread information **across all physician-administered drugs** than was provided by general studies on albuterol and the limited information of spreads for a limited number of other multi-source physician-administered drugs.

D. Defendants Incorrectly Assert that Private Sector TPPs with Staff Model HMOs Which Purchased Part B Drugs Were Sufficiently Knowledgeable to Defeat the Alleged AWP Inflation Scheme

12. If any entities would benefit from and act upon knowledge concerning the "mega-spreads" that existed between the AWPs and acquisition costs of drugs (spreads which are asserted by Defendants to be fully understood by the market), it would be profit-maximizing TPPs, particularly those which themselves purchased the same physician-administered drugs. One would expect that such profit-maximizing entities would be well informed and sufficiently economically agile to exploit such information and negotiate reimbursement rates to ASPs.

Indeed, Defendants put forward Dr. Gaier to demonstrate the verity of this assertion. He claims that "Knowledge regarding the differences between AWP and provider acquisition costs, as a matter of economic theory, would prevent payors from overpaying for prescription drugs as a result of the alleged AWP scheme and therefore insulated them from economic harm" (at his ¶ 4). **This conclusion is incorrect.**

13. Dr. Gaier analyzed sales data for "four of the top five Massachusetts TPPs[35] [that] purchased physician-administered drugs directly through contracts with manufacturers, through group purchasing organizations (GPOs), or through drug wholesalers. These purchases were made by organizations that provided medical care, required a supply of drugs for their operation, and were owned by these TPPs" (at his ¶ 6).

He found that these TPPs purchased "significant volumes of physician-administered drugs" (at his ¶ 7) ... "at discounted prices generally at, and in many cases below, the ASPs calculated by plaintiffs' expert Dr. Hartman" (¶ 8).

[35] He focuses on four TPPs in Massachusetts (BCBS MA, Harvard Pilgrim, Cigna and Fallon) which account for approximately 70% of covered lives in Massachusetts. BCBS MA accounts for 46%. See Dr. Gaier's Table 1.

He concludes (at his ¶ 9) that "manufacturers' sales data demonstrates that at least four of the largest five TPPs in Massachusetts ... had knowledge that the subject physician-administered drugs were available to providers at substantial discounts from AWP and knew the magnitude of those discounts since at least 1991." Dr. Gaier **incorrectly concludes** that "[t]his ... information ... would have caused payors to have 'negotiated more aggressively than they did, leading to lower reimbursement rates.'"

14. But this logic fails. Dr. Gaier simply has not **completed the necessary analysis to draw the conclusion that he and Defendants draw.** His analysis has merit **only if he demonstrates these direct purchases truly did inform** the TPPs of the **actual acquisition costs** paid by the staff model HMOs and that those TPPs made use of that information in their claims reimbursement practices. **Dr. Gaier does not conduct that analysis.**

15. I do. I demonstrate that the reimbursed amounts paid by the largest Massachusetts TPP (BCBS MA) **were not informed** by this knowledge of ASP. These BCBS MA reimbursement amounts were related to AWP in the same way as found with claims reimbursed by TPPs without staff model HMOs. The only valid conclusion that Dr. Gaier can draw from a complete analysis, which is also supported by deposition testimony,[36] is that this staff-HMO information was not shared in any meaningful way with claims administration generally, for the reasons discussed below.

16. In order to perform a more complete analysis, I had my staff gather and analyze the data summarizing claims administered outside of the staff-model HMO setting for one of the four Massachusetts TPPs, BCBS MA, which was the only TPP for which data were available. My analysis of the BCBS MA claims data focuses upon the period 1994-2003 and summarizes the average reimbursement amounts paid for a subset of the drugs and J-Codes that Dr. Gaier introduces. My analysis is presented in Attachment B.[37]

If Dr. Gaier's hypothesis is correct, I should find the following:

a) For those drugs which it purchased directly, BCBS MA should have been well-informed concerning acquisition costs and should have been able to make use of

[36] See ¶ 18 below and Attachment F.

[37] Attachment B describes the data and my implementation of the analyses. The drugs that I analyze in Attachment B that BCBS MA purchased directly are Vepesid, Zofran, Procrit, Blenoxane and Kytril. The drugs that I analyze that Dr. Gaier infers BCBS MA did not purchase directly are Zoladex, Taxol and Remicade (Dr. Gaier does not report direct prices for these three drugs). If Dr. Gaier's hypothesis is true, then the reimbursement amounts paid by BCBS MA for the first set of drugs certainly should track the ASPs rather than AWPs. Likewise, given Dr. Gaier's expansive belief in the power of available information to enable TPPs to negotiate better reimbursement amounts, we should find that BCBS MA was able to negotiate reimbursement rates that approximate the ASPs rather than the AWPs of those physician-administered drugs that it did not purchase directly.

The analysis of claims data rejects Dr. Gaier's hypothesized power of information to negotiate better reimbursement rates. For the drugs Vepesid, Zofran, Procrit, Kytril, Taxol and Remicade, average reimbursement rates are uniformly very close to or greater than AWP or 95% of AWP. For the drugs Blenoxane and Zoladex, average reimbursement rates are within approximately 15% of AWP, the range found by the MedPAC Report.

that information to negotiate reimbursement rates that approximated BCBS MA's EACs (or ASPs). Apparently they do not.

b) Even if BCBS MA did not purchase certain physician-administered drugs directly, the pricing and market information that it obtained from its purchase of other physician-administered drugs should have enabled BCBS MA to aggressively negotiate reimbursement rates closer to drug acquisition costs than to traditional reimbursements formulae based off AWP. Apparently they do not do this either.

17. Based upon my analysis, I find the following. The analysis of claims data **rejects Dr. Gaier's hypothesized power of information** to negotiate better reimbursement rates. Average reimbursement rates are either very close to or greater than AWP or they are within approximately 15% of AWP, the range found by the MedPAC Report. I conclude:

a) **Dr. Gaier is wrong** when he claims that TPPs with subsidiaries or divisions that purchase physician-administered drugs can make use of that information to better negotiate reimbursement rates for those insured lives that are not served by the staff model HMO.

b) Nothing in Dr. Gaier's Declaration proffers factual evidence that TPPs with direct purchasing of physician-administered drugs were better able, or at all able, to avoid the economic impact and injury of the AWP inflation scheme.

c) There is no evidence of **direct learning** by BCBS MA. Direct learning would occur if a drug purchased by a staff-model HMO informed other TPP reimbursement in the non-staff-model HMO divisions. For those drugs purchased by the BCBS MA staff-model HMO, the average reimbursement amounts track AWP not ASP. While each drug exhibits some idiosyncratic behavior, the evidence provides a powerful demonstration that the market for pharmaceuticals is characterized by non-transparency. Pricing patterns are opaque even **within** sophisticated buyers, such as BCBS MA.

d) Likewise, and not surprisingly, there is no evidence of **indirect learning**. Indirect learning would occur if a staff-model HMO learned of the AWP-ASP spread for a given set of drugs, conveyed that information within the TPP generally, and the non-staff-model divisions extrapolated that knowledge to gain some inferences about the ASPs related to claims for reimbursement for other drugs. I find that the reimbursement rates for other drugs reimbursed by BCBS MA track AWP rather than ASP.

e) To summarize, the fact that some division of an institution possesses certain pricing information that could benefit the institution generally does not automatically mean that the information will be transmitted or shared.

f) Various reasons may explain this lack of communication or learning:

- Dr. Berndt's Importance of Being Unimportant[38]
- The computer systems used to implement the reimbursement formulae for physician-administered drugs are too difficult to easily alter given specific cost information related to a specific drug.[39]
- The fact that the BCBS MA staff HMO knew **its** acquisition costs of physician-administered drugs likely provided a poor signal for the acquisition costs of **many small to mid-sized oncology/provider groups**, whose acquisition costs are the basis for the reimbursement amounts. Hence, BCBS MA may simply rely upon the AWP formula, since its internal information may have little relevance to its non-staff model provider claims.
- Finally, even if BCBS MA knew acquisition costs, when reimbursing for Medicare or MediGap Supplemental Claims, such knowledge of ASP would not be useful to Medicare to negotiate better reimbursement rates.

g) If **private TPPs** with **within-institution** pricing information cannot exploit that information to negotiate better reimbursement rates that more closely reflect acquisition costs (ASPs) rather than AWPs, it is highly unlikely (as discussed above) that the **government (HCFA and Medicare)** could exploit **outside-institution** pricing information (from diffused, less-focused, more-general surveys about the spreads on a limited number of physician-administered drugs) to better negotiate reimbursement rates and defeat the alleged AWP inflation scheme.[40]

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[38] See for examples ¶ 60.c) and footnote 31 of my December 15, 2005 Declaration on Liability and Calculation of Damages; and ¶¶ 57.c) & 69 and footnotes 24 & 115 of my December 16, 2004 Rebuttal Declaration.

[39] As stated in ¶ 2.e of Attachment K to my December 15, 2005 Declaration on Liability and Calculation of Damages (**emphasis added**), "In his ¶ 49, Mr. Young correctly observes 'The use of AWP by commercial Health Plans as a benchmark for expressing reimbursement limitations for prescription drugs dispensed to the plans' members expanded in the 1980's. The expanded use corresponded with (i) the growth of private insurance coverage for prescription drugs, (ii) the increased implementation of computer programs to manage the large volume of claims relating to drugs dispensed from retail pharmacies, and (iii) the shift from indemnity type coverage (based on pharmacy or physician 'charges') to coverage based on negotiated reimbursement rates (discussed in detail below). **The published benchmark provided a standardized and programmable means of implementing claims processing systems that could handle the wide-ranging discounts negotiated with individual pharmacies for millions of retail pharmacy claims.**'"

As shown in the Deposition of Michael T. Mulrey, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, January 5, 2006, the several reimbursement schedules used by BCBS-MA for physician administered drugs did not differentiate among physicians, but rather relied on Medicare as the common basis for reimbursement (pp. 50 – 64). Specifically, see Attachment F, Mulrey Quote 1.

See also, Declaration of Robert P. Navarro in Opposition to the Plaintiffs' Motion for Class Certification, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, United States District Court, District of Massachusetts, MDL No. 1456, Civil Action No. 01-12257, ¶ 46.

[40] These results certainly belie GSK's assertion in its Motion for Summary Judgment that "the relevant party at which the AWP was directed and who set reimbursement on the basis of this AWP – the Medicare program acting under standards set by Congress – was sophisticated and well-informed about the nature of AWPs" (*GSK Motion for Summary Judgment*, p. 15).

As I discussed with regard to what HCFA and Medicare knew and whether they could act upon it (see ¶ 11.k) above), the point is that institutional knowledge is slow to be disseminated, if disseminated at all, and even slower to be acted upon. It has been this slowness or complete inertia on the part of private TPPs that has been exploited by Defendants through the AWP inflation scheme.

18. Deposition testimony supports these conclusions.

a) For example, the deposition testimony of Michael T. Mulrey, Manager of Provider Reimbursement at Blue Cross-Blue Shield of Massachusetts (BCBS MA), provides clear indication that his understanding (prior to 2004) of AWP differed from what AWP actually was.

> Q. I am asking what your understanding was. Okay? Let's just start with that point. In 2000, what was your understanding of the term AWP, or average wholesale price?
> A. It is the price that we would reimburse our providers, and it was the price at which we felt providers purchased their drugs at.
> Q. Okay. So it is your understanding -- it was your understanding in 2000 that it was the price at which providers purchased their drugs; is that correct?
> A. Yes.
> Q. So, in other words, it is your position that you understood that Blue Cross/Blue Shield of Massachusetts was reimbursing providers at their average cost?
> A. Yes. (pp. 87-88)
> ...
> Q. So in 2003-2004, as a member of the provider reimbursement group, you learned that AWP was no longer, you know, from your perspective an average of actual wholesale costs but indeed was something greater than the costs that doctors paid for drugs; right?
> A. Yes. (p. 93)[41]

b) Furthermore, Mr. Mulrey's testimony clearly demonstrates BCBS MA realized it had been deceived once it became clear to them how different their reimbursement rates were from the published AWPs.[42]

It is interesting to note that Dr. Gaier cites in his Appendix D, Mr. Mulrey's deposition (pp. 11-17, thereof), which he purports establishes that BCBS MA had a staff HMO unit, and that they sent their P & L's to the parent BCBS organization. However, Dr. Gaier fails to cite the next few pages of Mr. Mulrey's testimony which indicates that despite this institutional connection, Mr. Mulrey did not gain an understanding of the costs at which physician-administered drugs could be obtained.[43]

c) Mr. Mulrey's testimony demonstrates that price and cost information did not readily flow within this organization, and as a result, BCBS MA was unaware of

[41] Mulrey Deposition, January 5, 2006.

[42] See Attachment F, Mulrey Quote 2.

[43] See Attachment F, Mulrey Quote 3.

specific information regarding rebate policies and discounts that manufacturers offered to physician providers.

d) For another example, Robert C. Farias, the director of planning administration for network services and operations at Harvard Pilgrim, in his October 20, 2004 Deposition states that Harvard Pilgrim was unaware of physician acquisition costs. The Farias deposition states that Harvard Pilgrim did not investigate physician acquisition cost. Furthermore, given the contract that Harvard Pilgrim enters into with any given physician or physician group, they would be unable to do anything other than reimburse according to the terms of the contract, in this case at 95% of AWP.[44]

e) Mr. Farias' testimony further demonstrates Defendants could take advantage of the reimbursement practices of TPPs. Once a TPP like Harvard Pilgrim enters into contracts with physicians that specify drug reimbursements according to fee schedules based on AWP or 95% of AWP, Harvard Pilgrim has felt bound by that contract. As a result, physicians knew that their spreads were guaranteed. Even if Harvard Pilgrim had become aware of the fact that physicians were receiving large discounts, Harvard Pilgrim would not alter its established institutional practice regarding negotiated reimbursement rates.[45]

E. Defendants Incorrectly Assert that Reliance of Generic Reimbursement Upon the Median Generic AWP Defeats Any Benefits Alleged to Flow from the AWP Inflation Scheme

19. Defendants rely primarily upon Dr. Addanki's analysis for this assertion. At ¶ 10, Dr. Addanki incorrectly asserts: "The plaintiffs' theory of AWP manipulation makes no economic sense whatsoever for generic drugs when reimbursement for such drugs depends on median AWPs. No generic manufacturer has any economic incentive to inflate AWP, because even if it could affect the median AWP, all generic competitors would be reimbursed at the new median AWP, yielding no competitive advantage to the manufacturer who 'inflated' its AWP."

20. Dr. Addanki bases this incorrect assertion upon an incomplete understanding of the market and flawed data analysis in his ¶¶ 31-32, 37-43. Based upon his analysis, I conclude that Dr. Addanki has not fully grasped the formulaic methodology that I introduced in my September 3, 2004 Declaration in Support of Class Certification and implemented in my December 15, 2005 Declaration on Liability and Calculation of Damages. Specifically,

a) At ¶ 12 of my September 3, 2004 Declaration, I state, "From an economic standpoint, based upon the allegations in the *Complaint*, the Defendant Drug

[44] Deposition of Robert C. Farias, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, October 20, 2004. See Attachment F, Farias Quote 1.

[45] See Attachment F, Farias Quote 2.

Manufacturers' motives in this matter were simple. They are alleged to have acted with others to manipulate relevant drug prices in order to incentivize the relevant market entities to purchase (or 'move market share' of) their drug products and thereby increase aggregate profits earned on the increased sales."

The AWP scheme at issue involved artificially inflating the list price of the relevant drugs (AWP, and by implication any list price and any end-payer reimbursement rate formulaically linked to AWP) while reducing the actual acquisition cost of the drugs to the relevant provider, thereby increasing the spread earned by the provider of drugs. This increased spread incentivized the relevant providers to prescribe more of the relevant drugs relative to alternative therapies, everything else equal. This increased spread caused patients/consumers to be switched to higher-priced products or to continue purchasing drugs at prices that did not reflect true costs or cost reductions, a result at odds with competitive market outcomes.

Indeed, recently published scientific evidence supports this contention. In Jacobson, *et al.*, it is noted that "Once a decision to give chemotherapy was taken, however, physicians receiving more-generous Medicare reimbursements used more-costly treatment regimens."[46]

b) As I have postulated throughout my testimony, what moves market share and what was the focus of branded and generic manufacturers to move market share was the **spread, not the AWP alone**. Hence, Dr. Addanki is wrong when he asserts at his ¶ 31 that "Unlike the case of branded drugs – where AWP or WAC may represent a list price – AWPs play little role in the case of generic drugs." As I demonstrate in Attachment E to my September 3, 2004 Declaration, spread moves generic market share, not AWP alone. The spread is determined by manufacturers aggressively reducing their ASPs to providers **relative to a fixed median AWP** (which is the basis for reimbursement).[47]

c) Because **spread competition** (generated by falling ASPs of generic drugs) is the important determinant in moving generic market share, Dr. Addanki's analysis (¶ 43 and footnote 24) of **AWP competition** between Schering's Proventil and Warrick's albuterol has absolutely no meaning.

d) Specifically, **Dr. Addanki proposes his own theory**, specifically that AWP alone moves market share. Using **his theory,** he deduces that the higher AWP of Proventil should increase Proventil's market share. He finds (at ¶ 43) that the "evidence [pertaining to Proventil and albuterol] seems at odds with" his theory.

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[46] Mireille Jacobson, A. James O'Malley, Craig C. Earle, Juliana Pakes, Peter Gaccione and Joseph P. Newhouse, "Does Reimbursement Influence Chemotherapy Treatment for Cancer Patients?" *Health Affairs*, 25:2, March/April 2006, pp. 437-443; at p. 442.

[47] Indeed, as I cite at length in ¶ 53 of my December 15, 2005 Declaration on Liability and Calculation of Damages, the MedPAC Report indicates that the preferred method by which drug manufacturers manipulated the spread was inflating AWP relative to a constant ASP. However, when AWP inflation did not prove possible, the alternative was to lower the ASP relative to a constant AWP.

e) Having proposed and refuted **his theory** of AWP competition, he **improperly attributes that theory to me** and concludes that the evidence "seems at odds with" that theory.

f) Put simply, Dr. Addanki has attributed a theory to me that I have never proposed. He has refuted a theory that I have never proposed. His analysis and conclusions have no relevance to the theory I have proposed and which the data support. It is that competition and the realities of generic competition generally that lead to the market penetration of Warrick's albuterol relative to Proventil found in the evidence.

21. As I develop more fully in Section III, it is also clear that Dr. Addanki has presented a distorted analysis of the median AWP.

a) His analysis grossly overstates the real variation in the generic AWPs and the median. My more complete analysis demonstrates that the relevant dispersion is much more focused.

b) It is interesting to note that Dr. Addanki chose to present the AWPs he includes using a bar graph as shown in Figure 1 below. This type of presentation obscures the clustering of the AWPs for most of the generics. Figure 2 below presents the **same** information but using a scatter-plot series for each generic NDC. In Figure 2 it is obvious that most of the AWPs reported by Dr. Addanki cluster around the median. In fact, the three highest points for each year belong to a repackager who sells their product in an atypical unit dose which according to CMS regulations is not to be included in the calculation of the median.[48] Excluding this repackager, Dr. Addanki's graph would look like that presented in Figure 3, clearly a very different picture than Dr. Addanki has presented.

[48] See sections 20.4 and 20.5.5, Calculation of the AWP in the CMS Manual System, Pub. 100-04 Medicare Claims Processing Department of Health & Human Services (DHHS), Centers for Medicare & Medicaid Services (CMS), Transmittal 397, December 16, 2004, Change Request 3232: "In applying this procedure [calculation of median], carriers use the package sizes that are most commonly used for the most frequently administered dosage of the drug."

Figure 1

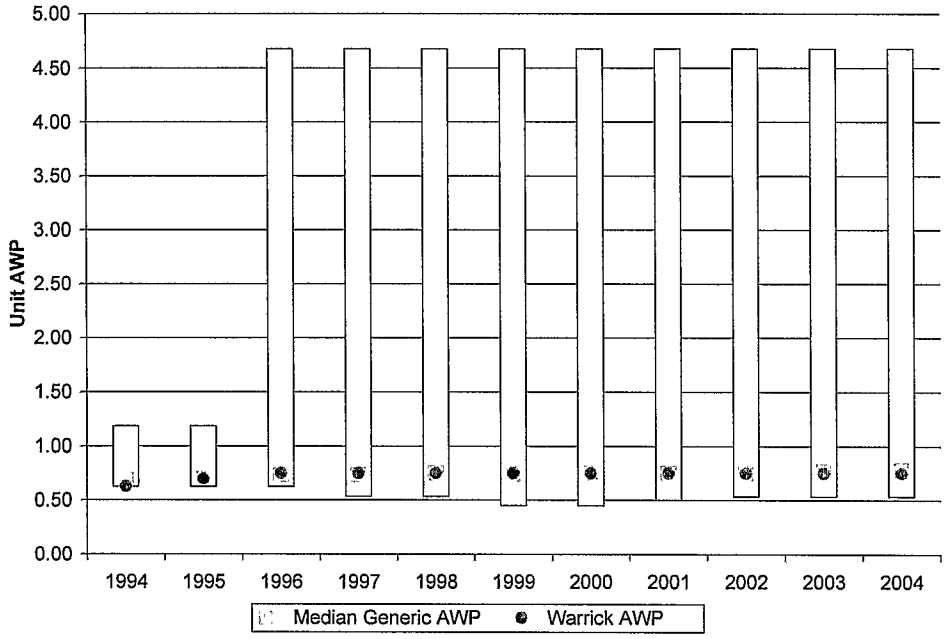


Figure 2

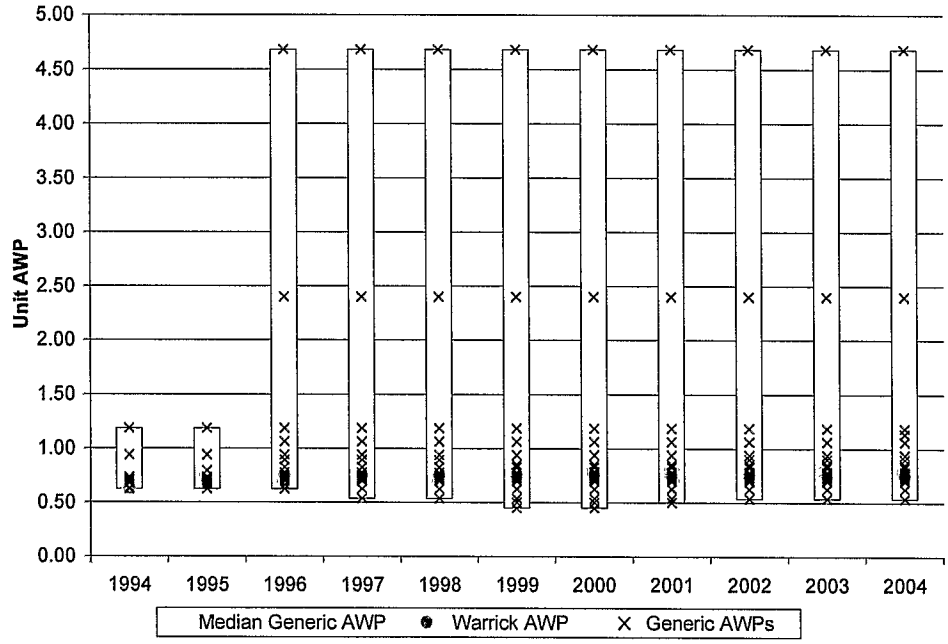
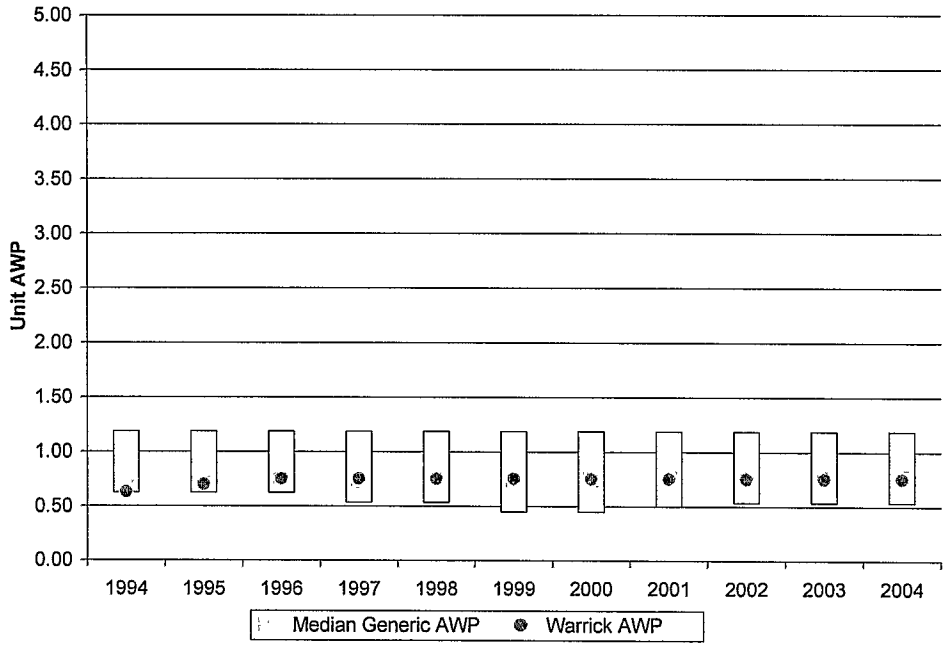


Figure 3



c) My analysis indicates that contrary to his claims,[49] the Warrick AWP is the median in many cases. This is illustrated in Figures 1 - 3 where the median is marked with a square and the Warrick AWP with a circle.

d) While Dr. Addanki is correct when he states (¶ 40), "no individual manufacturer has any incentive to attempt to 'inflate' its AWP,"

- It is true that **all** generic manufacturers of a given drug have the incentive to maintain the median AWP as high as possible, to increase the spreads of all manufacturers relative to potential **alternative therapeutic competitors**.
- It is true that **all** generics launch with an AWP fairly close to the AWP of the related branded drug (by NDC). In most cases, the generic AWP is some 5-15% below the branded AWP, although in some cases, a generic AWP may be greater than the branded AWP. The precise setting of the AWP may be determined by the timing of the generic entry.
- It is true that once the generic manufacturers set their AWPs, most manufacturers maintain them at constant levels.[50]

[49] At his ¶ 39, he asserts "Indeed, the AWPs for Warrick's albuterol products are at the lower end of the range of AWPs," certainly implying that they are below the median. At ¶ 43, he asserts "The AWPs for these [Warrick's] albuterol products are generally at or below the median of the prices of products with a similar product description."

- The result seems to be a tacit Nash equilibrium in the dispersion of generic AWPs, which are fairly similarly discounted off of the branded AWP for which the generics are equivalent, a Nash equilibrium not unlike that noted by Dr. Berndt with regard to the observed similar relationship between AWP and WAC over most branded drugs.[51] Once the dispersion is set, the generic manufacturers compete amongst themselves on spread through the reduction of their ASPs.

- The apparent Nash equilibrium in the dispersion of generic AWPs is linked to the AWP of the branded drug for which those generics are bioequivalent. Hence, the entire dispersion, including the median, is artificially inflated to the extent that the branded AWP is artificially inflated. This observation is certainly relevant to the dispersion and median of the AWPs for albuterol, since they have been set relative to Proventil's AWP. To the extent that the median is thereby inflated, the spreads of generic albuterol will be further inflated relative to any ASP.

F. Defendants Assert that the Alleged Behavior Is Economically Rational and Imply Therefore that Economic Rationality Trumps the Law

22. Defendants rely primarily upon Dr. Bell to make this argument, who defends the alleged AWP inflation scheme for BMS as reflecting economic rationality, standard business practices and/or competitive practices.[52]

a) At ¶ 7.b) of his Declaration, Dr. Bell asserts that "[t]he BMS list prices are determined in a manner that is consistent with standard economic behavior." He argues that BMS sets the list price based on market research at launch, and

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[50] For example, Schering-Plough-Warrick confirms this in their Concise Statement of Undisputed Material Facts in Support of Schering-Plough Corporation's and Warrick Pharmaceuticals Corporation's Motion for Summary Judgment, March 15, 2006. At ¶ 36, they state "Warrick suggests an AWP at launch and has, in almost all instances, not changed the AWP for the life of the product Weintraub. Decl.¶¶ 11, 13; Addanki Decl. ¶44." At ¶ 42, they state "Since 1995, Warrick's AWPs for 0.083% and 0.5% solutions of albuterol have stayed the same. Addanki Decl. ¶44, Exs. 4A-B."

[51] In commenting on the consistent relationship between the list prices AWP and WAC, Dr. Berndt in his Report of February 2005 states (at p. 10), "In summary, for brand name/single source self-administered drugs, while the underlying rationale supporting a 20-25% spread between AWP and WAC has long disappeared, manufacturers and retailers appear to be locked in to this practice. In the jargon of economics and game theory, what we observe is a Nash equilibrium in which for all players AWP exceeds ASP and WAC. There is no incentive for any brand name manufacturer of self-administered single-source drugs to align its AWP to a level much closer to WAC."

In this case, what we observe for generic drugs is a dispersion of AWPs related to the AWP of the brand name drug for which the generic drugs are equivalent. No single generic will attempt to influence the median. The greater the spread between the ASPs and the median AWP, the more competitive will be **all generics** in that group **relative to** the **generics of therapeutic substitutes,** everything else equal. Competition among generics within that group will be driven by the spread created by ASP competition.

[52] I further discuss the "standard economic practices" aspect of this claim in Section III.C below.

increases the list price over time based on market conditions. Once generic competition occurs, BMS keeps the price constant.

b) "To the extent that price concessions [by BMS] to particular customers increased over time, these were generally in response to pricing pressures brought forth by generic competition" (at his ¶ 7.d).

c) "Once the product loses patent exclusivity, average price concessions increase as BMS competes for the business of certain preferred providers" (at his ¶ 31.c).[53]

d) "To the extent that BMS and/or OTN [Oncology Therapeutics Network] sales representatives explain the relationship between acquisition cost and reimbursement to their physician customers, that is consistent with standard economic behavior. ... It is economically beneficial for that to happen" (at his ¶ 7.e).

e) "The sales representatives for BMS and OTN were responsible for much of the interaction with physicians and physician offices regarding the products at issue in this litigation. These interactions focused on product information but also included discussions of acquisition cost and reimbursement, particularly when new information on acquisition cost or reimbursement issues needed to be disseminated. In my opinion, the provision of information regarding acquisition cost and reimbursement is not only commercially reasonable, it is to be expected from a standard business perspective" (at his ¶ 59).

f) "If a sales representative provides accurate information to the physician on the economics of the transaction, that enhances competition" (at his ¶ 67).

g) "Under some circumstances, most often as a result of therapeutic or generic competition, BMS engages in sales transactions to segments of the market at prices that are below the list price.... Nonetheless, it would not be economically rational for BMS to lower the list price; to do so would be to lose revenue on the sales to those physicians and hospitals that were continuing to pay at or about list price" (at his ¶ 7.c).

h) "The only remaining question is whether BMS should reduce its list prices as average transaction prices decline. In my opinion, such action would not be economically rational. Even after a product becomes subject to generic competition, there remains a segment of customers that continue to be willing to pay at or about the list price for the branded product.... Finally, to the extent that payors choose to reimburse based on the AWPs reported by the pricing publications, BMS could not be expected to report a price other than the WLP to the pricing publications" (at his ¶ 25).

23. **It is true** that the pricing behavior and detailing behavior (by sales representatives) described by Dr. Bell can be considered to **constitute economic**

[53] For example, he defends the large spreads on Taxol post-generic-launch as a rational economic response to generic competition: "When generic competition was looming in 2000, BMS ... hired CRA to help with strategy development. ... In sum, BMS did not seek to maximize spread on Taxol. Rather, BMS took a disciplined approach to the advent of generic competition" (¶¶ 43 and 48).

rationality. If such behavior did not appeal to economic rationality, it would not have been successful. I have demonstrated this in Attachment E to my September 3, 2004 Declaration in Support of Class Certification. Dr. Rosenthal has recognized this in her testimony.[54]

However, economic rationality does not trump the law. The relevant question is whether such rational economic behavior is legal.

a) It may be **economically rational** for several large manufacturers that dominate a particular market to explicitly or tacitly collude to fix prices and increase profitability even though **it is not legal.**

b) It may be **economically rational** for a particular manufacturer to systematically discriminate against older members of its work force (who have greater seniority, larger salaries and higher health care costs) with respect to promotions, further salary increases and termination even though **it is not legal.**

c) It was certainly considered **economically rational** for TAP to engage in the RICO violations with respect to Lupron, violations to which they pled guilty since **the violations were not legal.**

d) During times of crisis such as Hurricane Katrina a variety of shortages arise, including gasoline, water and food shortages. There certainly were gasoline shortages that were made public; more people wanted to buy gasoline than gasoline stations could serve. **Rational economic behavior** argues that gas station owners (and refiners) would rationally raise prices. However, some states have laws against "unconscionably excessive" prices in times of emergency.

e) In all of these cases, **economically rational business entities** would weigh the advantages of the profit-maximizing but **potentially illegal economic behavior** against the costs and probability of being caught and punished. In all four cases, if the fines for violation are deemed small and/or the probability of being caught is deemed low, then the **economically rational yet illegal behavior** could very well be **a rational economic decision.**[55]

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[54] Indeed, Dr. Rosenthal finds that "there were strong economic incentives for the Defendants to have engaged in the allegedly unlawful AWP inflation, a fact corroborated by documents produced by Defendants. These incentives, coupled with the general lack of price transparency in the market for the drugs in question, created an environment in which AWP inflation would be ***economically rational behavior*** for a pharmaceutical manufacturer" (Liability Report of Dr. Meredith Rosenthal, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, December 15, 2005, p. 1, emphasis added).

[55] An economic study of the gasoline market (by Severin Borenstein and Richard Gilbert of the University of California at Berkeley and A. Colin Cameron of the University of California at Davis) looked at the extent to which retail gas prices respond to changes in crude oil prices and wholesale gasoline prices and the extent to which gouging occurs. They found that gasoline price gouging was most prevalent when wholesale prices started to fall and retail prices remained high, a situation not unlike that alleged here, where we observe falling ASPs and unresponsive AWPs determining reimbursement rates. See Severin Borenstein, Richard Gilbert and A. Colin Cameron, "Do Gasoline Prices Respond Asymmetrically to Crude Oil Price Changes?" *Quarterly Journal of Economics*, Vol. 112, No. 1, February 1997.

More generally, the fact that an act is economically rational does not necessarily mean or imply that it is legal. If an economic agent believes that an act is illegal but considers the probability of being caught low

f) It is certainly **economically beneficial** for BMS

- To offer substantial discounts, rebates and price concessions to providers to move market share in the face of therapeutic and generic competition.[56]
- To direct its sales representatives to meet with providers, to discuss and accurately inform those providers about those substantial discounts, rebates and all other types of price concessions offered to market share.
- "To [direct] ... BMS and/or OTN sales representatives [to] explain the relationship between acquisition cost and reimbursement to their physician customers" (his ¶ 7.e).
- To maintain and increase the list price of its products (WLP and AWP) and thereby maintain or increase the spread earned by the physician providers on BMS branded and generics drugs.
- To maintain and increase the list price of its products (WLP and AWP) because "to lower the list price ... would be to lose revenue on the sales to those physicians and hospitals that were continuing to pay at or about list price" (his ¶ 7.c).
- To maintain strict confidentiality regarding the extent of the discounts, rebates, price offsets and concessions offered to specific providers and overall, so that the providers could maintain the spread and not lose it in negotiation with payors.[57]

g) However, note that all economically beneficial actions cited by Dr. Bell **benefit providers not consumers**. BMS "competitively" increases the knowledge of the providers; BMS "competitively" lowers the prices to the providers. None of these economically rational actions benefit the consumers in this market – the Class

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and/or the cost or penalty having been caught as low and the benefits of the act sufficiently great, then engaging in that illegal act could be considered economically rational. Moreover, if benefits remain the same, but the act is legally ambiguous, then the probability of being caught and punished will be that much lower.

[56] Indeed, Dr. Bell and his consulting company, CRA, was employed by BMS to help implement rational economic pricing strategies that targeted spread competition to the appropriate groups of providers. Dr. Bell states (at ¶¶ 51-52), "there were substantial price concessions on VePesid for [i]njection once it became multi-source.... In contrast, VePesid capsules, not confronting generic competition until 2001, experienced price concessions that averaged no more than five percent. Even after generic etoposide capsules were approved, price concessions were relatively minor, average ten percent in 2002." This price (spread) discrimination illustrates the differential incentives that exist for physicians to move market share of physician administered drugs when the spread was substantial while such incentives were not compelling for self-administered capsules. See Attachment E of my September 3, 2004 Declaration in Support of the Certification of Class.

[57] This effort to *surreptitiously* offer discounts was an explicit strategy of TAP in the Lupron scheme; see *Lupron Sentencing Memorandum,* pp. 26-27.

members.[58] Consumer knowledge is not increased; consumer reimbursement rates are not reduced.

h) While **economically beneficial** to BMS, these actions on the part of BMS **are alleged to be illegal** precisely because they cause reimbursement rates paid by Class members to be substantially higher than they would have been absent the AWP scheme. They seem to be felt to be **economically rational** because BMS has believed that it would not be caught or punished for these allegedly illegal acts.

G. Expressing the Spread Relative to ASP or AWP is Equivalent

24. In his Declaration, Dr. Addanki incorrectly implies that had the spreads used in my analysis of liability and the calculation of damages been expressed relative to AWP, the resulting mega-spreads would evaporate. Specifically, he argues (at ¶ 8, with supporting discussion at ¶¶ 33-36) that "[t]he 'spreads' calculated by the plaintiffs' expert are very misleading; using an 'ASP' base, rather than the more commonly used AWP base, greatly exaggerates the apparent size of the 'spreads.'"

His arguments fail for the following reasons.

a) For purposes of finding causation and liability, **it is irrelevant** whether the spread is calculated off AWP or ASP. I have made that clear in my September 3, 2004 Declaration in Support of Class Certification at ¶ 20 as follows:

> "To the extent that the alleged AWP scheme was effectuated by Defendants, they would reveal themselves in 'excessively' large spreads or deviations between the inflated AWP and the transaction price (ASP) for which the AWP is taken as a signal. These spreads can be measured as (AWP – ASP), (AWP/ASP), (AWP – ASP)/AWP or (AWP – ASP)/ASP;[59] the precise measure used will depend upon the analytic needs of the formulaic models."

b) Indeed, Dr. Addanki provides the concordance between the two definitions of spread: the threshold for liability for spreads based upon ASP is 30%; the threshold for a finding of liability for spreads based upon AWP is 23%.

c) If measured consistently, every drug subject to a finding of causation and liability under the ASP-based spread of 30% will be subject to a finding of causation and liability under the AWP-based spread of 23%. The measure of damages using

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[58] I have explained how spread competition differs from normal welfare enhancing competition in ¶ 15.h) of my December 16, 2004 Rebuttal Declaration.

[59] Note that in the last two forms, the measure of spread resembles the Lerner Index, a standard economic measure of revealed market power. Note also that in most business calculations, the notion of unit profitability is the measure of (unit revenue – unit cost)/unit cost; therefore as a matter of business practice, I defined the spread as I did. This is certainly a definition used by Defendants when appropriate; see for example, the BSM sales report (BMS/AWP/01406365), which states "message … loud and clear. Bottom line, he wants us to raise our AWP or lower our price. I told him that our AWP is about 25% over acquisition costs, and that we are one of the best in terms of AWP."

either yardstick will be **identical,** as I demonstrate in Attachment D where I discuss this issue in greater detail.

d) Since the spread is calculated as (AWP – ASP)/(AWP or ASP), the largest spread that can occur relative to AWP is 100% (if ASP = 0), whereas, the largest spread calculated relative to ASP can be much greater (indeed, infinitely large if ASP = 0). Assuming ASP is not 0 but is equal to say 5 and AWP = 100, then (AWP – ASP)/ ASP = 1900%, whereas (AWP – ASP)/AWP = 95%.

e) While this seems to matter greatly to Dr. Addanki, as a matter of business practice and economics **it does not matter at all.** Relative to ASP, 1900% is a mega-spread; relative to AWP, 95% is a mega-spread. The AWP and ASP are the same. The finding of causation and liability will make use of the same AWP and ASP, only expressed differently. **The measure of damages will be identical.**

f) For perspective, Dr. Addanki could have expressed my damage calculations in pennies and argued that my calculation therefore exaggerated damages. Neither that argument nor his argument has economic content.

H. Questions Addressing Data Issues

25. Several experts raise detailed questions concerning my use of their clients' data, including questions about the correct apportionment of rebates; the correct apportionment of sales subject to Medicare and non-Medicare reimbursement; inclusion of appropriate entities as Class members; inclusion of appropriate classes of trade; and others. I discuss selected data issues in more detail in Section III for Dr. Bell and Mr. Dukes. Broadly speaking,

a) The Declaration of Mr. Dukes simply argues that he has more and better data than I do. During my damage analysis, I asked for but did not receive all information necessary for me to fully implement my analysis of causation and liability and my calculation of damages. Mr. Dukes certainly has better access to J&J data than I have had.[60] In order to respond to his criticisms, I will need to review and analyze his data and any notes and work papers that he has generated. Note that Plaintiffs only received some of his backup materials two days prior to the submission of this declaration. I have not reviewed these materials. Until that time, I cannot offer an opinion concerning the correctness or incorrectness of his assertions regarding the J&J data.

b) Dr. Bell raises questions on a variety of issues including my inclusion of sales to particular entities in the calculation of ASPs, my assumption about certain generic launch dates, my apportionment of sales to Medicare and non-Medicare payors

[60] Declaration of Jayson S. Dukes in Support of the Johnson & Johnson Defendants' Motion for Summary Judgment as to Class 1 and Class 2, March 15, 2006, ¶ 47, "My staff and I posed numerous data-related questions to Johnson & Johnson's counsel and to knowledgeable individuals at various Johnson & Johnson operating companies. Their responses enabled us to resolve numerous issues that were otherwise indeterminate. Dr. Hartman's staff presumably encountered many of the same issues, but had to resolve them without having commensurate access to company personnel."

and my treatment of missing data. In order to respond fully to his criticisms, I will need to review and analyze the notes and work papers that he has generated. Note that Plaintiffs have not yet received the notes and work papers that he relied upon.

In either case, nothing I have reviewed to date would cause me to change my opinions regarding my formulaic methodologies or the process of calculating damages based on those methodologies.

I. The Fact that BMS Did Not Report AWPs to the Price Reporting Services Is Not Relevant

26. The BMS Motion for Summary Judgment asserts that BMS never reported AWPs. They conclude thereby that BMS could not have participated in the AWP inflation scheme. Instead, BMS claims to have reported the WAC (or wholesale list price – WLP) to the relevant price reporting services and did not control the resulting calculation or dissemination of AWPs by those price reporting services.

In support of this argument, BMS argues that 86% of BMS's net revenues for "the drugs at issue" were from transactions with transaction prices within 5% of WLP.[61] This fact is not telling.

a) Most of BMS's drugs would be distributed through wholesalers who would purchase at or around the WLP. Plaintiffs are focused upon branded and generic physician-administered drugs that are usually distributed to providers not wholesalers. If the drugs are distributed through specialty pharmacies or wholesalers to providers, those drugs are subject to substantial price offsets which make the WLP irrelevant as a transaction price. The price offsets are reflected in the deeply discounted contract prices to provider groups for which wholesalers are compensated through chargebacks.

b) Indeed, it is likely that the AWP inflation scheme occurred on a subset of drugs that accounted for the remaining 14% of BMS net revenue, and that inflation was facilitated by the price expectations set by the drugs within the 86% of net revenue.

27. BMS argues there was and is no legal responsibility for it to include discounts in list prices or to report discounts. They claim if and when BMS's sales force discussed spreads, such discussions were not intended to move market share but were merely responses to customer questions.

These assertions have been made before and have been demonstrated to be incorrect before. As a matter of economics, list prices are some of the most important signals that all drug manufacturers, particularly innovator drug manufacturers, use to strategically place drug products in the market. The two most important list prices are the AWP and the WAC (or WLP). As I stated in Attachment D (¶ 1) to my September 3, 2004 Declaration in Support of Class Certification: "Almost all pharmaceutical

[61] *BMS Motion for Summary Judgment*, pp. 4-5, relying upon the Bell Declaration at ¶¶ 7.a) and 24.

reimbursement formulae make use of AWP. AWP is the glue that binds the system of reimbursements; it is the common unit of measurement for negotiating almost all reimbursement rates allowed by private sector and public sector insurers."[62] The Court has certainly conceded this point.[63] Since there is a well understood formulaic relationship between AWP and WAC,[64] reporting **either** to the price reporting services implies that **the other list price is set automatically**. The argument that BMS would report only its WAC (WLP) and pay no attention to the resulting AWP set by the pricing services is implausible and not credible, as a matter of economics and the business practices in this industry and market.[65]

III. Additional Analysis of Selected Issues

A. Dr. Addanki's Claim that Plaintiffs Assert that AWP Should Equal ASP is Unfounded

28. As further discussion to Section II.A above, I elaborate on Dr. Addanki's incorrect claim that Plaintiffs assert AWP should equal ASP. Beginning almost immediately, in his ¶ 7, Dr. Addanki initiates his flawed arguments (which he develops more fully in his ¶¶ 20-26) as follows:

> "As to Classes 1 and 2, the plaintiffs' theories of liability, causation, and damages are logically inconsistent, contradict basic economics, and lead to absurd conclusions. Specifically:
>
> - The plaintiffs' assertion that the average wholesale price ('AWP') should equal 'ASP' is fatally flawed.
> - There is no basis for asserting that the manufacturers' average selling prices ('ASPs')-the price paid by wholesalers-should equal prices charged by wholesalers (which is what the plaintiffs' allege AWP should represent).
> - Insisting upon this equality contradicts basic economic principles and leads to absurd conclusions.

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[62] As stated by Dawn Gencarelli, in "Average Wholesale Price for Prescription Drugs: Is there a More Appropriate Pricing Mechanism?," HHPF Issue Brief, No. 775/June 7, George Washington University, 2002, (pp. 2-4), "Though imperfect, the AWP has come to represent a starting point for determining prescription drug reimbursement for public and private payers. … The AWP, or average wholesale price, of prescription drugs was intended to represent the average price at which wholesalers sell drugs to physicians, pharmacies, and other customers. … The AWP has often been equated with a 'sticker price' or 'list price,' as those terms are used in the automobile industry." The wholesale acquisition cost (WAC – discussed in the text) is "often referred to as the 'catalogue' price" (p. 15). A variety of other prices relevant to the industry are defined and discussed by Ms. Gencarelli in her *Glossary* (p. 15).

[63] See pp. 9-10 of the *Memorandum and Order* in this matter.

[64] See ¶ 2, Attachment D of my September 3, 2004 Declaration in Support of Class Certification; and ¶ 5 of this Declaration.

[65] Furthermore, it is contradicted by BMS documents. See BMSAWP/0011245-8 as cited in my December 15, 2005 Declaration of Liability and Calculation of Damages, Attachment F, p. 10.

- AWP must necessarily exceed 'ASP' for every pharmaceutical product on the market; insisting upon their equality implies that every drug on the market is liable under the plaintiffs' test, contrary to the plaintiffs' own assertions."

29. This litany of four "logically inconsistent … theories … and absurd conclusions" is either stunningly misinformed or represents a brazen mischaracterization of my testimony to date.

a) Neither I nor Plaintiffs have ever asserted that the AWP should equal "ASP" (the first bullet point above), either as a matter of statute or as a matter of the business practices in this market. Indeed, I (and Plaintiffs) have asserted that as a sticker price or signal for other list prices and transaction prices, **AWP is always greater than ASP and has formed the basis for reasonable predictions of ASP.**

b) In Section I ("Overview – the Average Wholesale Price (AWP) is the Pricing Benchmark for the Industry") of Attachment D to my September 3, 2004 Declaration in Support of Class Certification, I state at ¶¶ 1-2 (with added footnotes),

"1. The Average Wholesale Price (AWP) is the list price that manufacturers of prescription drugs report to the publishers of the pricing compendia used for pricing information by direct and indirect purchasers and all other entities in the markets for prescription drugs. The three most-commonly used price compendia reporting AWPs are The Red Book (published by Thomson), Medispan, and First Data Bank (which publishes the Blue Book). Almost all pharmaceutical reimbursement formulae make use of AWP. AWP is the glue that binds the system of reimbursements; it is the common unit of measurement for negotiating almost all reimbursement rates allowed by private sector and public sector insurers.

2. AWP plays the role of the benchmark price in the industry, from which discounts and rebates are negotiated between manufacturers and direct and indirect purchasers.[66] It is closely, indeed usually formulaically, related to another list price, the Wholesale Acquisition Cost (WAC). By industry practice, AWP is equal to 120% or 125% of WAC (the choice of mark-up depends upon the manufacturer). Because the two list prices are usually related by a constant ratio, they convey the same information to purchasers and other entities that rely on published price data. That is, AWP and WAC are interchangeable as the basis for beginning to negotiate allowable reimbursement rates. For example, a third-party payer might agree to reimburse a retailer for brand name drugs at AWP minus 10% or, equivalently, at WAC plus 8%; the negotiated reimbursement rate or allowable amount will be exactly the same."[67]

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[66] See footnote 62 above.

[67] Assuming AWP = 120% of WAC for the drug in question, AWP = 1.2*WAC. If the allowable amount is AWP minus 10%, then it is equal to (1.00 - .10)*AWP = .90*AWP. But AWP = 1.2*WAC; therefore, the allowable amount = .90*(1.2*WAC) = 1.08*WAC = WAC plus 8%.